PATENT

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Denise C. Cheung

Appellant	:	J. Christopher Marmo	Confirmation No. 1370
Application No.	:	10/811,690	
Filed	:	March 29, 2004	
Title	:	HYDROGEL CONTACT LENSES AND PACKAGE SYSTEMS AND PRODUCTION METHODS FOR SAME	
Grp./Div.	:	1796	
Examiner	:	Nathan M. Nutter	
Docket No.	:	1128-01-PA-TD	
Customer No.	:	79567	

APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

43 Corporate Park, Suite 204
Irvine, CA 92606
June 3, 2008

Commissioner:

This is an appeal to the Board of Patent Appeals and Interferences from the Final Rejection, dated December 5, 2007, in which Claims 172-178 and 186 of the above-referenced application stand rejected. A Notice of Appeal was filed on March 3, 2008.

1. REAL PARTY IN INTEREST

CooperVision, Inc.

2. RELATED APPEALS AND INTERFERENCES

There are no related Appeals and/or Interferences.

3. STATUS OF CLAIMS

Claims 172-178 and 186 are finally rejected and are on appeal. Claims 1-171 and 179-185 were previously cancelled.

4. STATUS OF AMENDMENTS

No amendments in response to the Final Office Action of December 12, 2007 have been presented.

Claims 172-178 and 186 were previously presented.

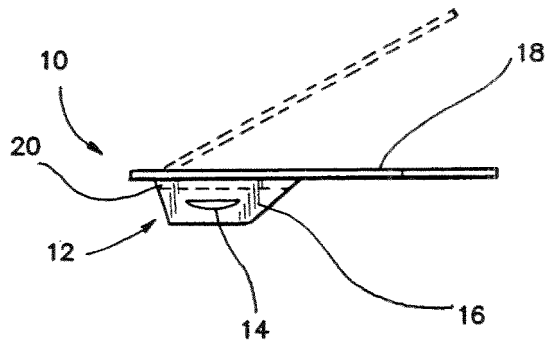
5. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 172 is an independent claim.

Independent claim 172

Claim 172 is directed to a package system comprising a disposable hydrogel contact lens and a sterile packaging liquid medium. FIG. 1 of the application, which is reproduced below, shows an embodiment of the package system as claimed.

FIG. 1



According to claim 172, the package system 10 includes a container 12, a contact lens 14, including a contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component (WSPC), a sterile liquid medium 16, which comprises an aqueous saline solution containing a separate amount of the same WSPC present in the contact lens, and a removable seal 18. According to claim 172, the WSPC present in the contact lens 14 and the sterile liquid medium 16 comprises a polyalkylene glycol. (Specification, page 14, lines 20-27).

Dependent claim 176:

Claim 176 depends from claim 172. According to claim 176, the water soluble polymer component (WSPC) is physically immobilized by the hydrophilic polymeric material (Specification, page 4, lines 2-4 and page 9, lines 30 to page 10, line 3), so that the WSPC is replaced by water substantially only after the lens is placed in an eye.

Dependent claim 177

Claim 177 depends from claim 172. According to claim 177, the water soluble polymer component (WSPC) and the hydrophilic polymeric material form an interpenetrating network or a pseudo interpenetrating network (Specification, page 4, lines 4-7 and page 10, and lines 4-8) to provide the desired degree of physical immobilization of the WSPC.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 172-178 and 186 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al (U.S. Application No. 2001/0044482), Gordon (U.S Patent No. 4,123,408), or Shah (U.S. Patent No. 4,462,665), each taken in view of Dziabo (U.S. Patent Nos. 5,338,408) and Krezanoski (U.S. Patent No. 3,954,644).

Claims 172-178 and 186 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al (U.S. Patent No. 6,008,170) or Salpekar et al (U.S. Patent No. 6,440,366), each taken in view of Dziabo and Krezanoski.

Appellant respectfully requests review of independent claim 172 and separately patentability of dependent claim 186.

7. ARGUMENTS

A. §103(a) Rejection of Claims 172-178 and 186 by Hu et al, Gordon or Shah, each taken in view of Dziabo and Krezanoski

The above-identified claims are rejected as unpatentable under §103(a) over the cited references.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983) (emphasis added); MPEP 2141.02(I). Distilling an invention down to a "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 3030 (Fed. Cir. 1983); MPEP 2141.02(II). As held by the Board of Patent Appeals and Interferences in *Ex parte* Wada and Murphy (Appeal No. 2007-3733, decided January 14, 2008), "[w]hen determining whether a claim is obvious, an examiner must make "a searching of the claimed invention - *including all its limitations* - with the teaching of the prior art. *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333,

1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)". "[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 USC § 103." In re Sponnoble, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969) (emphasis added); MPEP 2141.02(III). "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR International Co. v. Teleflex, Inc.*, 550 U.S. at ___, 82 USPQ2d 1385, 1396 (2007).

Appellant submits that the present claims are unobvious and are patentable at least because (i) the cited references do not teach or suggest all of the features recited in the present claims, and (ii) a person of ordinary skill in the art would not be motivated to modify the references or combine the teachings of the references, as proposed by the Examiner. At a minimum, the cited references do not teach or even suggest the combination of a contact lens that contains a polyalkylene glycol and a contact lens packaging solution that contains the same polyakylene glycol, as recited in the present claims.

In addition, the inventor has identified a problem that was not recognized by the cited references. One problem identified is the migration of specific compounds from the contact lens body into the surrounding packaging liquid medium, which can result in a decreased compound concentration in the contact lens body when it is finally worn. It is believed that the reduced concentration of the compound results in diminished beneficial effects of the compounds to the eye, such as by reducing contact lens surface lubrication and decreasing comfort to the wearer of the contact lens.

In the instant application, benefits of using the WSPCs in the manufacture of the contact lens body include for example:

> ... to provide enhanced lubrication to the eye wearing the contact lens and/or to increase the comfort to the lens wearer of wearing the contact lens relative to an identical contact lens without the WSPC (page 7, line31 to page 8, line 3).

Given the above-identified benefits of the WSPCs, it is therefore highly desirable to maintain their respective concentrations in the contact lens body so that the contact lens will have the desired properties upon being worn by the user. However, a problem previously unrecognized by the prior art was identified by the inventor of the instant application, that is WSPCs can be water-displaceable (Specification, page 9, lines 24-25). Therefore, anytime a contact lens containing one or more WSPCs is placed in a liquid medium consisting primarily of aqueous solution, such as the water wash after the polymerization step, or in the packaging liquid medium, or eventually in the eye, the WSPCs can be replaced by water.

This displacement by water inevitably reduces the concentration of WSPCs in the contact lens body, thus diminishing their positive properties to the eyes upon being worn by the user.

Once the as yet unrecognized problem of WSPCs migration from the contact lens body to the surrounding liquid medium resulting in an attenuation of their desired properties had been identified by the inventor of the instant application, several remedies to address the problem were described in the instant application, including:

1. Adding the WSPCs in the polymerization step, as described in:

> Such methods comprise polymerizing, preferably solution polymerizing at least one hydrophilic monomeric component in the presence of a WSPC to form a contact lens body comprising a hydrophilic polymeric material and the WSPC. The WSPC preferably is included in a diluent used during the polymerizing step. (Specification, page 12, lines 20-26)

2. Eliminating the solvent displacing step. Routinely, after the polymerization is complete, the solvent is displaced with water. However, to minimize the migration of WSPCs from the polymerized contact lens body into the wash solution, the instant application discloses eliminating the solvent displacing step, as described in:

> Thus, the present methods of making hydrogel-containing contact lenses are even less complex and more economical, for example, by eliminating the solvent displacing step, relative to prior art direct molding processes discussed elsewhere herein (Specification, page 2, lines 26-30)

which results in:

> One important feature of the present methods is that the WSPC is not replaced, for example, with water, prior to the contact lens being placed into a packaging container or into an eye (Specification, page 13, lines 9-12)

3. Adding an amount of the WSPC in the liquid packaging medium in addition to that present in the contact lens body. After manufacture, the contact lens is placed in a packaging liquid medium for an amount of time before being worn by the contact lens user. During this storage time, which can be days or weeks or months, the WSPCs migrate from the contact lens body to the surrounding liquid medium according to their concentration gradient (from more concentrated to less concentrated), until equilibrium is reached. Thus, after recognizing this migration as a problem that causes the final concentration of WSPCs in the contact lens body to decrease significantly, the instant application teaches:

> The liquid medium comprises an amount of the WSPC in addition to the WSPC present in the contact lens body. Advantageously, the liquid medium includes the WSPC prior to the liquid medium being placed in contact with the lens body. The presence of the WSPC in the liquid medium preferably is effective to inhibit migration of the WSPC in the lens body form the lens body. Thus, the amount or concentration of the WSPC in the lens body is substantially maintained in contact with the liquid medium 16. (Specification, page 13, line 24 to page 14, line 1).

Appellant submits that the cited references do not provide any indication of the recognition of the problem of WSPCs migration from the contact lens body into the surrounding packaging liquid medium to result in a loss, or reduction, of beneficial properties. In view of the foregoing remarks, Appellant respectfully submits that the claimed package system is NOT directed merely to a package system of disposable hydrogel contact lens, a sterile packaging liquid medium, and a container holding the contact lens and the sterile packaging medium, which the Examiner has reduced independent claim 172 to recite. The instant invention "as a whole" is directed to a package system having a unique contact lens and packaging solution combination ("...water soluble polymer component in addition to that present in the contact lens body..."). The claimed package system solves a problem that was not previously recognized or identified by the prior art. Independent claim 172 can also be thought of as reciting a package system for providing a contact lens that will leach less of its beneficial properties overtime due to the same

lens composition as package solution, which results in a lower concentration gradient between the contact lens and the package solution to yield a lower loss of beneficial properties. This concept is clearly set forth in the language: "a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body..."

Accordingly, as further discussed below, Appellant submits that the Examiner has improperly distilled the claimed invention down to a "gist" or "thrust" and thus has disregarded the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 3030 (Fed. Cir. 1983); MPEP 2141.02(II). None of the cited references recognized product leaching as a problem due to incompatible packaging solution or the efficacy of selecting a package solution having the same WSPC in addition to that present in the contact lens body to solve such a problem. The thrust of this discovery is recited in claim 172, which among other things, claims "...water soluble polymer component in addition to that present in the contact lens body..."

1. Description of Hu et al

The 2001/0044482 Hu application discloses hydrogel contact lenses comprising an interpenetrating polymer network (IPN) composition. The IPN comprises at least one polymer which is formed through the polymerization of monomers, and at least one IPN agent. Monomers that could be used in the formation of the polymer include a long list of various compounds (paragraphs [0019] and [0029]). IPN agents include but are not limited to polyvinylpyrrolidone (PVP) or poly-2-ethyl-2-oxazoline (PEOX) or poly(4-vinylpyridine N-oxide) (PVNO) or their mixtures (paragraph [0019]).

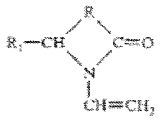
The Examiner contends that the claimed contact lens is disclosed in Hu's publication on the basis that similar monomers and agents are used in the manufacture of both the claimed and referenced contact lenses.

2. Description of Gordon

The '408 Gordon patent discloses hydrogel contact lenses comprising various polymers which can be worn in the eye with minimum discomfort or irritation (Col. 2, lines 42-45 and col.

4, line 45 to col. 5, line 10). The contact lens disclosed by Gordon can be obtained from hydrogels wherein the polymer is from:

> A) A water-soluble polymer of a heterocyclic N-vinyl polymerizable compound containing carbonyl functionality adjacent to nitrogen in the ring (see figure below); and
>
> B) a polymerizable mixture containing:
>
> 1) polymerizable monoester of acrylic and/or methacrylic acid and polyhydric alcohol;
>
> 2) an alkyl acrylate and/or alkyl methacrylate and/or vinyl ester; and
>
> 3) as cross-linking agent, divinyl benzene and/or divinyl toluene. (col. 2, line 45-55)

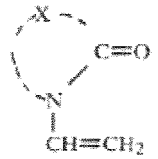


Gordon is relied on to disclose contact lenses which are similar to the claimed contact lenses as they are formed from similar monomers and/or agents. It should be noted however that Gordon specifically teaches how to make lathed contact lenses (col. 9, lines 19-25). As would be obvious to one of ordinary skill in the art, lathed contact lenses are physically different and distinct from cast molded contact lenses recited in the claimed packaging system. Thus, the fact that the claimed contact lens and the lenses disclosed by Gordon are distinct to a person of ordinary skill in the art makes the obviousness rejection defective and clearly lacking a prima facie case.

3. Description of Shah

The '665 Shah patent discloses polymer blends capable of forming hydrogels which are compatible with vinyl lactam polymers to form laminates. The polymer blends is described in col.2, lines 1-37, as reproduced below:

The invention comprises a composite article comprising (A) a layer of an optically clear blend of (1) 40 to 98% by weight, based on the total weight of the blend, of a water-soluble polymer of a vinyl lactam having the structure



in which X represents an alkylene bridge having three to five carbon atoms, or a water-soluble copolymer thereof, with 1 to 90 mole percent of copolymerizable monomer containing a polymerizable ethylenic unsaturation, said polymer or copolymer having a molecular weight from 10,000 to 1,000,000 and (2) 2 to 60% by weight of a water-insoluble copolymer consisting essentially of 50 to 90% by weight, based on the total weight of the copolymer, of a hydrophobic water-insoluble ethylenically unsaturated monomer, 2 to 12% by weight of an ethylenically unsaturated monomer containing an acid group, and 0 to 50% by weight of a hydrophilic ethylenically unsaturated monomer free from acidic groups, and (B) adherent thereto a layer of solid high molecular weight water-resistant polymeric material which is compatible with said vinyl lactam polymer or copolymer as determined by optical clarity of a mixture in the unhydrated state of said polymeric material with said vinyl lactam polymer or copolymer, said layers being in face to face adherent contact with each other, and said layer (A) being capable of absorbing more than 45% of its weight of water without dissolution at room temperature to form a hydrogel adherent to layer (B).

As described, Shah specifically teaches how to make laminated contact lenses (col. 7, line 55 to col. 8, line 62). The Examiner contends that the claimed contact lenses are disclosed by Shah but Appellant respectfully points out that, as would be obvious to one of ordinary skill in the art, laminated contact lenses are physically different and distinct from cast molded contact lenses recited in the claimed packaging system. As before, the fact that the claimed contact lens and the lenses disclosed by Shah are distinct to a person of ordinary skill in the art makes the obviousness rejection defective and clearly lacking a prima facie case.

4. Description of Dziabo

The '480 Dziabo patent is directed to contact lens cleaning solutions using enzymes. Generally speaking, contact lens cleaning solutions contain disinfectants that are incompatible with many enzymes, thus can reduce the enzymes' effectiveness. To overcome problems associated with disinfectant/enzyme incompatibility, the '480 Dziabo patent discloses compositions comprising enzymes and disinfectant destroying component to destroy the disinfectant that interferes with the activity of the enzyme, after the lens has been disinfected by said disinfectant. To allow the disinfectant sufficient time to perform its function, the '480 Dziabo patent also teaches using delayed release components that serve to delay the release of enzyme and disinfectant destroying components relative to the disinfectant.

The Examiner relies on Dziabo to disclose contact lens storage solution. However, it should be noted that cleaning solutions are fundamentally different from the packaging solution of the claimed packaging system, as further discussed below.

5. Description of Krezanoski

The '644 Krezanoski patent is directed to silicone and hydrogel contact lens cleaning, storing and wetting solutions, which comprise block copolymer of polyoxyethylene - polyoxypropylene, microbial growth inhibitor such as benzalkonium chloride (Abstract), salt solution such as 0.5 to 1.8 percent sodium chloride (Abstract), and optionally metal chelators such as disodium or trisodium ethylenediamine tetraacetate (Abstract) and a polymeric viscosity builder such as hydroxyethyl cellulose (col. 4, line 40-42).

6. The combination of Hu or Gordon or Shah and Dziabo or Krezanoski does not render claims 172-178 and 186 obvious as required under §103(a)

In rejecting claims 172-178 and 186, the Examiner states on page 3 of the Office Action:

> The primary references, [Hu, Gordon or Shah], teach the contact lens of the claims. The secondary references, [Dziabo and Krezanoski], show the solution for cleaning/storage and show such as conventional, as recited herein. The employment of a package is notoriously obvious since the product must be vended and distributed. As such, a skilled artisan would have a high level of expectation or success following the teachings of the references.

The Examiner rejects the claimed package system on the basis that the references to Hu, Gordon or Shah show the contemplated contact lens and the references to Dziabo and Krezanoski show the storage and cleaning of contact lenses using polymers. However, Appellant respectfully submits that by merely focusing on the comparison of the claimed contact lens by itself to the referenced contact lens and the claimed liquid packaging medium by itself to the referenced storage/cleaning solutions, the Examiner has distilled the invention down to a 'gist' or 'thrust' and thus has disregarded the requirement of analyzing the subject matter 'as a whole' (MPEP 2141.02, II). As the Federal Circuit has held, distilling an invention down to a "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 3030 (Fed. Cir. 1983), and "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Furthermore, as the following remarks will illustrate, Appellant respectfully submits that not only do the individual references cited by the Examiner fail to disclose the claimed contact lens and the claimed packaging medium, even if erroneously combinable, the cited references still fail to render the pending claims obvious as they fail to disclose all the elements and limitations of the pending claims. Still furthermore, when viewing the claimed package system "as a whole", the cited references, either individually or in combinations, do not disclose, suggest, or contemplate, the efficacy of using a package solution having the same water soluble polymer component as a single use disposable hydrogel contact lens having a lens body comprising a hydrophilic polymeric material and the water soluble polymer component.

In 2007, the KSR Supreme Court reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Furthermore, according to MPEP §2141, "Office personnel . . .[to perform the] critical role of factfinder when resolving the *Graham* inquiries. . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person

of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness."

Under 35 U.S.C. 132, a well articulated and reasoned Office Action is required so that an applicant may be properly notified of the reasons for the rejection of the claim so that he or she can then decide how best to proceed. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). MPEP §2141(III).

Once Office personnel have established the *Graham* factual findings and conclude that the claimed invention would have been obvious, the burden then shifts to the applicant to (A) show that the Office erred in these findings or (B) provide other evidence to show that the claimed subject matter would have been nonobvious. Examples of rebuttal evidence include (MPEP §2141(V)):

(A) one of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);

(B) the elements in combination do not merely perform the function that each element performs separately; or

(C) the results of the claimed combination were unexpected.

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). MPEP §2143.02.

Among other things, Appellant submits that compliance with 35 U.S.C. § 132 has not been established. For example, and at a minimum, none of the Office Actions dated May 26, 2006, March 14, 2007, or December 12, 2007 include any clearly articulated or reasoned indication where in the cited references is any solution, let alone a packaging solution, containing a polyalkylene glycol as recited in the present claims. In addition, the Office Actions do not identify where in the cited references polyethylene glycol is disclosed in a solution, let alone a packaging solution, as recited by dependent claim 186. Without this clear articulation of how the present claims are rendered obvious by the cited references, Appellant respectfully submits that the present rejections under 35 U.S.C. § 103 are in error and cannot be properly maintained (*KSR*, supra).

Independent claim 172 recites a package system comprising: a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol. (emphasis added)

Thus, among other features, claim 172 specifically recites that the cast molded contact lens AND the packaging liquid medium comprise the SAME water soluble polymer component. Appellant respectfully emphasizes that the limitation of the SAME water soluble polymer component being present in both the contact lens body and the liquid packaging medium is important to the claimed invention, as the presence of the SAME WSPC in the packaging liquid

medium and the contact lens body reduces or completely eliminates the migration of the valuable WSPC from the contact lens body to the surrounding liquid medium, thus maintaining the concentration of WSPC in the contact lens body and maximizing its beneficial effects to the contact lens wearer. Furthermore, even if a prior art reference or a combination of references teaches a lens and a packaging liquid having the same water soluble polymer component, according to claim 172, which Appellant does not concede, the water soluble component must be a polyalkylene glycol.

The cited primary references for a contact lens (Hu, Gordon and Shah) disclose monomers and polymers commonly used in the manufacturing of contact lenses, which include vinyl-lactams such as N-vinylpyrrolidone, methacrylic acid, 2-hydroxyethylmethacrylate, 2-hydroxyethylacrylate, etc. In the final Office Action dated 12/05/07, the Examiner alleged that the "primary references teach the contact lens of the claims" (page 4, final Office Action). However, after carefully reviewing the cited references, Appellant respectfully points out that none of the primary references teaches or discloses the inclusion of polyalkylene glycol in their contact lenses, as clearly recited by the rejected independent claim 172. In addition, none of the cited references teaches or suggests the claimed package system, wherein the polyalkylene glycol is polyethylene glycol, as recited by dependent claim 186. Should the Examiner insist that the cited references disclose or suggest all the features of the claimed contact lens, Appellant respectfully requests that the Examiner provides specific references (by page, column, line number, or paragraph number) to such disclosure in compliance with MPEP § 2260 and 37 CFR §104(c)[1], which requires a clear and complete Office Action.

The Examiner relies on Dziabo or Krezanoski to disclose storage solutions. As described above, the Dziabo patent and the Krezanoski patent are directed to cleaning solutions containing enzymes or disinfecting agents. Neither Dziabo nor Krezanoski provide the deficiencies

[1] (c) (2) In rejecting claims for want of novelty or for obviousness, the Examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified. (emphasis added)

apparent in the primary references, and do not disclose contact lenses that contain a polyalkylene glycol.

Furthermore, Appellant submits that the Dziabo patent and the Krezanoski patent do not disclose contact lens packaging solutions, as recited in the present claims.

Appellant respectfully submits that cleaning solutions, as taught by the Dziabo patent and the Krezanoski patent, are different and distinct from packaging solutions, even if they happen to contain similar ingredients. Indeed, packaging solutions and cleaning solutions are not viewed as interchangeable by a person of ordinary skill in the art. Packaging solutions are regulated by the FDA as part of the initial contact lens package and therefore must remain sterile until use. US 6,440,366 (the '366 patent), one of the cited references, clearly highlights these differences: "[Non-ionic surfactants] are well-known wetting and lubricating agents for contact lenses and have been used in lens wetting drops and in lens-care solutions for treating lenses after use" (Col. 1, lines 42-47) and "[f]urthermore, the difficulties of adding a surfactant to a packaging solution, including the possibility of lowering shelf-life and/or adverse reactions during heat sterilization, have further limited the use of surfactants in a packaging solution. . ." (Col. 2, lines 17-21). A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). See also MPEP §2141.02(VI).

In short, there are components that are suitable for a cleaning solution but not for a packaging solution. One example is enzymes, which are essential ingredients in the cleaning solutions disclosed by Dziabo. The intended function of enzymes in such cleaning solutions, as described above, is to facilitate the removal of proteins or other deposits formed on the surface of the contact lens, which accumulate only after the lens has been worn. In an unused contact lens, there is no protein deposit, thus there is absolutely no need to include enzymes in a packaging liquid medium. Another reason that would preclude the inclusion of enzymes in a packaging solution is, as the subsequent remarks will further illustrate, due to very stringent sterilization requirement imposed by the FDA, the enzymes will likely be destroyed by the sterilization process.

Similarly, disinfectants are required in cleaning solutions to clean contact lenses but are unsuitable in packaging solutions. Indeed, disinfectants play a vital role in cleaning solutions in that they reduce or eliminate microorganisms or microbial growths to protect the lens wearer from infection. However, disinfectants are unsuitable to the eyes and can cause eye irritation. Should disinfectants come in contact with a contact lens, it needs to be rinsed before it can be worn again as cleaning agents can cause eye irritation. On the other hand, a lens package with packaging solutions is subject to stringent sterilization requirements and therefore unlikely to have microbial growths, which makes disinfectants superfluous or unnecessary. Still furthermore, stringent FDA regulations are imposed on packaging solutions and as summarized in the '366 patent, and they "must be 'ophthalmically safe' for use with a contact lens, meaning that a contact lens treated with the solution is generally suitable and safe for direct placement on the eye without rinsing" (Col. 4, lines 52-55). Thus, while disinfectants are required for cleaning solutions, they are clearly unsuitable for packaging solutions, further substantiating the argument that components or ingredients used in packaging solutions and cleaning solutions are NOT interchangeable.

In view of the above-described FDA guidelines and remarks, Appellant respectfully disputes the Examiner's position that Dziabo and Krezanoski show the packaging liquid medium of the claimed packaging system when in fact they are directed to cleaning solutions.

Furthermore, even if the references are combinable, a position Appellant strongly refutes, any combination of Hu, Gordon or Shah and Dziabo and Krezanoski does not disclose all the elements and limitations of the pending claims. Nowhere in any of the references, either individually or in any permissible combination, is disclosed or suggested a package system comprising: a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol. (emphasis added). Similarly, nowhere in the cited

references is disclosed or suggested the package sytem of claim 172, wherein the polyalkylene glycol is polyethylene glycol, as recited by claim 186. Again, Appellant respectfully emphasizes that the key limitation of having the same WSPC in the contact lens body and the liquid packaging medium is essential to the instant invention, as this limitation is responsible for minimizing the migration of the WSPC from the contact lens body to the surrounding liquid medium.

Furthermore, even if a reference discloses the use of a polyalkylene glycol, among a very long list of available compounds, in the manufacture of the contact lens or in the cleaning/storage solution, Appellant respectfully submits that that there is no motivation or suggestion for one skilled in the art to use the SAME compound in the packaging solution, given that the problem dictating that the SAME WSPC be used in the contact lens body AND the packaging solution was not apparent to one of ordinary skill in the art until identified by the instant application. "[I]n cases involving new chemical compounds, [such as here where a new package system comprising a lens body comprising a combination hydrophilic polymeric material and a water soluble polymer component comprising polyalkylene glycol placed inside a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present invent contact lens body is used], it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). As the Examiner has failed to articulate reasons for combining the references, it is clear the Examiner has erroneously reduced the obviousness analysis to an exercise in finding only the "gist" of the invention.

In addition, the Examiner's rejection would require that a cleaning solution be substituted for a packaging solution during the manufacturing process since the present claims are directed to packages containing contact lenses and a sterile packaging liquid. Thus, the proposed combination would require that the contact lens be packaged in a liquid medium (the cleaning solution) that also contains enzymes and disinfectants. The resulting package would need to be sterilized based on the FDA regulations, such as by conventionally autoclaving the packaged contact lenses (exposing to about 121 degrees C under steam pressure). The sterilization process

would negatively impact the enzymes since enzymes are proteins and tend to denature and become ineffective when exposed to elevated temperatures. Thus, the resulting solution in the sterilized package would be rendered inoperative for its intended purpose based on the teachings of the references.

Also, the effects of including enzymes and disinfectants under sterilizing conditions would require a series of validation studies to demonstrate that the presence of enzymes and disinfectants in the packaging solution would not negatively affect the properties of the contact lens and render them clinically unacceptable. Such validation studies require significant amounts of time, resources, and money to perform. Thus, "one of ordinary skill in the art could not have combined the claimed elements by known methods" due to the foreseeable difficulties in such an attempt. MPEP §2141(V).

In view of the above, it is clear that a person of ordinary skill in the art **would not be motivated** to substitute a contact lens cleaning solution for a contact lens packaging solution, especially when contact lens manufacturers and their employees are under pressure to produce contact lenses in short amounts of time with as low expenditures as possible. Given the fact that the Examiner's proposed "simple" substitution would require more time to produce a product, more resources to produce a product, and more money to produce a product, and in view of the FDA regulations the manufacturer must satisfy, a person of ordinary skill in the art would not be motivated to substitute a cleaning solution for a packaging solution as proposed by the Examiner, let alone to combine the teachings of a contact lens cleaning solution patent with the teachings of a contact lens patent or a contact lens packaging solution patent. Thus, the rejections are clearly in error and cannot be properly maintained.

This is even more significant for single use lenses or daily disposable lenses, as recited in the present claims. In order to supply single use lenses, the manufacturing costs are very significant and any effort that results in increased costs to produce single use lenses is typically frowned upon. Thus, a person of ordinary skill in the art would have even less motivation to substitute a cleaning solution for a packaging solution when the contact lens is a single use or daily disposable lens. Furthermore, since a single use lens is not prescribed to be worn more than once, a single use lens is not used with a cleaning solution. Therefore, a person of ordinary

skill in the art would not turn to a contact lens cleaning solution to solve a problem for a single use contact lens.

In view of the foregoing remarks, Appellant respectfully requests rescission of the §103(a) rejection of claim 172. Since claims 173-178 and 186 depend from claim 172, they too are allowable for at least the same reasons and allowance is respectfully solicited.

In addition to the patentability of claim 172, dependent claim 186 is separately patentable. Claim 186 recites: "The package system of claim 172, wherein the polyalkylene glycol is polyethylene glycol". As set forth above, none of the cited references, either individually or in any permissible combination, shows or suggests the specific species of polyethylene glycol either in the contact lenses or the packaging solution, let alone in BOTH the contact lenses AND the packaging solution. Thus, Appellant respectfully submits that even if combinable as suggested by the Examiner, the references fail to disclose all of the elements of claim 186. Accordingly, claim 186 is not rendered obvious by the cited references.

B. Rejection of Claims 172-178 and 186 under 35 U.S.C. 103(a) by Tanaka et al. or Salpekar each taken in view of Dziabo and Krezanoski.

In rejecting claims 172-178 and 186, the Examiner contends, on page 3 of the Office Action, that:

> The primary references, [Tanaka and Salpekar], teach the contact lens of the claims. The secondary references, [Dziabo and Krezanoski], show the solution for cleaning/storage and show such as conventional, as recited herein. The employment of a package is notoriously obvious since the product must be vended and distributed. As such, a skilled artisan would have a high level of expectation or success following the teachings of the references.

As set forth above, Appellant respectfully reasserts that by focusing on the differences between the individual components of the claimed packaging system and those disclosed by prior art, the Examiner has distilled the claimed invention down to a "gist" or "thrust" and thus has disregarded the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 3030 (Fed. Cir. 1983); MPEP 2141.02(II).). Therefore, Appellant respectfully requests reconsideration of the §103(a) rejection

on the basis of the invention 'as a whole' and NOT merely on the basis of the differences between the claimed contact lens and packaging liquid medium relative to contact lens and storage solutions disclosed by the prior art.

1. Description of Tanaka et al

The '170 Tanaka patent is directed to contact lens cleaning solutions comprising a protease in an amount effective for removing protein adhering or clinging to contact lenses, and gum arabic as a hydrophilicity rendering component, wherein divalent metal ions in the gum arabic are removed or inactivated (Abstract). The contact lens is immersed in such contact cleaning solution wherein the protease removes protein deposits from the contact lens and the gum arabic renders the contact lens hydrophilic. The function of the protease however is deteriorated by divalent metal ions, such as calcium and magnesium ions which are present in the gum arabic. To minimize the inhibitory action of the divalent ions on the protease, the '170 Tanaka patent teaches inactivating the divalent ions by chelation. (col. 3, lines 5-14).

On page 4 of the final Office Action, the Examiner states: "The reference to Tanaka et al (U.S. 6,008,170) shows the contemplated contact lens in the instant claims at the Abstract, the paragraph bridging column 3 to column 4, column 6 (lines 45-61), the Examples and claims". However, as the subsequent remarks will illustrate, the above-identified citation does NOT show the claimed contact lens.

2. Description of Salpekar

The '366 Salpekar patent is directed to hydrogel contact lens packing solution comprising non-ionic surfactants containing polyoxyalkylene copolymers, as clearly stated in the following paragraph:

> The gist of the invention is based on the discovery that a certain class of poly(oxyethylene)-poly(oxypropylene) surfactants are retained on the surface of an unused lens, resulting in surface modification of the lens that surprisingly persists in the eye for an extended period of time. Such surfactants can provide a significant improvement in the wetting properties and comfort of fresh contact lenses used for the first time (col. 3, line 11-18).

On page 4 of the final Office Action, the Examiner states: "The reference to Salpekar et al (U.S. 6,440,366) shows the contemplated contact lens in the instant claims at the Abstract, column 3 (line 53) to column 7 (line 57), the Examples and claims".

3. The combination of Tanaka et al or Salpekar et al and Dziabo or Krezanoski does not render claims 172-178 and 186 obvious as required under 103(a)

As set forth above, the Examiner relies on Tanaka et al or Salpekar et al to show the contact lens in the claimed packaging system and on Dziabo or Krezanoski to show polymers used in the cleaning/storage solutions.

In view of the above descriptions of the cited references, Appellant respectfully submits that not only do the individual references cited by the Examiner fail to disclose the claimed contact lens and the packaging medium, even if combinable, the references fail to render the pending claims obvious as they fail to disclose all the elements and limitations of the claimed package systems, as required by MPEP 706.02(j).

With respect to the disclosure of Tanaka et al., the Examiner cited, among others, the paragraph bridging column 3 to column 4 of Tanaka as disclosing "the contemplated contact lens employed in the instant claims". However, that paragraph primarily discloses a cleaning solution containing an additional thickener:

> In a further preferred form of the contact lens cleaning solution of the present invention, the cleaning solution further contains as an additional component a thickener such that an aqueous solution which contains only said thickener at the same concentration as a concentration of said thickener in said cleaning solution gives surface tension of not lower than 50 dyn/cm at ordinary temperature. The thickener is advantageously selected from the group consisting of: polyvinyl pyrrolidone, copolymer of methoxyethylene and maleic anhydride, xanthan gum, and hydroxyethyl cellulose. (Col. 3, line 62 to Col. 4, line 5).

Others citations referred to by the Examiner in the '170 Tanaka patent (i.e., Abstract, column 6 (lines 45-61), the Examples and claims) also disclose primarily a cleaning solution, as shown in the following paragraph (column 6, lines 45-61).

> To the present contact lens cleaning solution, there is further added a suitable thickener so as to give a suitable degree of viscosity to the cleaning solution, improve the touch of the cleaning solution and enhance

> a cleaning effect with respect to the lipid deposits. As the thickener to be added to the present cleaning solution, polyvinyl pyrrolidone, copolymer of methoxyethylene and maleic anhydride, xanthan gum or hydroxyethyl cellulose is preferably used. The cleaning solution contains as an additional component a thickener such that an aqueous solution which contains only the thickener at the same concentration as a concentration of the thickener in the cleaning solution gives surface tension of not lower than 50 dyn/cm at ordinary temperature. Accordingly, the addition of the thickener is effective to adjust the viscosity of the cleaning solution to a suitable value without adversely influencing the action of the gum arabic to render the contact lens surface hydrophilic.

Similarly, the Examples and the claims are all directed to a cleaning solution. Thus, Appellant respectfully disputes the Examiner's statement that the reference to Tanaka et al "show the contemplated lens employed in the instant claims".

With respect to the disclosures of Salpekar et al, the Examiner cited several references to show the "contemplated contact lens employed in the instant claims", such as the Abstract, column 3 (line 53) to column 7 (line 57) and the claims. The Abstract of Salpekar clearly states:

> The present invention is directed to new and improved solutions for packaging contact lenses and to methods for treating contact lenses with such solutions to improve the comfort of the lenses during wear".

Salpekar et al. does indeed disclose hydrogel contact lenses but merely to show which types of contact lenses would benefit from the claimed packing solutions and to describe the effect of the claimed packing solutions on the different contact lenses. Thus, contact lenses that are made from methacrylic acid (MAA), hydroethyl methacrylate (HEMA), or N-vinylpyrrolidone (NVP) are disclosed as lenses that could be used with the claimed packaging solution (col. 6, lines 55-62). However, nowhere in the '366 Salpekar patent is disclosed cast molded contact lenses comprising a water soluble polymer component which is polyalkylene glycol. Thus, Appellant respectfully disagrees with the Examiner's assertion that "[t]he reference to Salpekar et al (US 6,440,366) shows the contemplated lens recited in the instant claims".

The Examiner relies on Dziabo or Krezanoski to disclose cleaning and storage solutions. The disclosures of Dziabo and Krezanoski are discussed above. As set forth above, the FDA guidelines would teach a person of ordinary skill in the art away from using cleaning solutions

taught by Dziabo or Krezanoski as packaging solutions. Thus, Appellant respectfully disagrees with the Examiner that the references to Dziabo and Krezanoski show the packaging liquid medium of the claimed packaging system.

As the disclosure of Tanaka is directed to a cleaning solution and NOT to "the contemplated contact lens" as alleged by the Examiner, clearly it cannot be combinable with Dziabo and Krezanoski, which also disclose cleaning solutions to render the claimed package system, comprising in part a single use hydrogel contact lens and a sterile packaging liquid medium, obvious. Even if the hydrogel contact lens disclosed by Salpekar is assumed combinable with the cleaning and storage solution of Dziabo and Krezanoski, Appellant submits that the combination of Salpekar and Dziabo and Krezanoski does not disclose all the elements and features of the pending claims. None of the references, either individually or in any permissible combination, disclose or suggest a package system comprising: a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol. (emphasis added). Similarly, none of the references, either individually or in any permissible combination, discloses or suggests the package system of claim 172, wherein the polyalkylene glycol is polyethylene glycol, as recited by claim 186. Again, Appellant respectfully emphasizes that the key limitation of having the same WSPC in the contact lens body and the liquid packaging medium is important to the instant invention as it can help reduce the migration of the WSPC from the contact lens body to the surrounding liquid medium to thereby maintain beneficial properties for greater comfort to the user.

Furthermore, even if a reference discloses the use of a polyalkylene glycol among a very long list of available compounds in the manufacturing the contact lenses or in cleaning/storage solutions, Appellant respectfully submits that that there is no motivation or suggestion for one skilled in the art to use the SAME WSPC in the packaging solution, given that the problem

dictating the use of the same WSPC in the packaging solution is not apparent to one of ordinary skill in the art until identified by the instant application.

In view of the foregoing remarks, Appellant respectfully requests rescission of the §103(a) rejection of claim 172. Since claims 173-178 and 186 depend from claim 172, they too are allowable over the cited references for at least the same reasons and allowance is similarly solicited.

In addition to the patentability of claim 172, dependent claim 186 is separately patentable. Claim 186 recites: "The package system of claim 172, wherein the polyalkylene glycol is polyethylene glycol". As set forth above, none of the cited references, either individually or in any permissible combination, shows or suggests the specific species of polyethylene glycol either in the contact lenses or the packaging solution, let alone in BOTH the contact lenses AND the packaging solution. Thus, Appellant respectfully submits that even if combinable as suggested by the Examiner, the references fail to disclose all of the elements of claim 186. Accordingly, claim 186 is not rendered obvious by the cited references.

Conclusion

In view of the foregoing arguments, Appellant submits that claims 172-178 and 186 are patentable over the cited references and allowance is respectfully solicited.

Respectfully submitted,

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080602_Appeal Brief V4 with GSH comments D4109US.doc

8. CLAIM APPENDIX

1 - 171. (Cancelled)

172. (Previously presented) A package system comprising:

a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component;

a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and

a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol.

173. (Previously presented) The package system of claim 172, wherein the container comprises a cavity structured to hold the contact lens in contact with the liquid medium.

174. (Previously presented) The package system of claim 172, wherein the liquid medium includes the water soluble polymer component prior to the liquid medium being placed in contact with the contact lens.

175. (Previously presented) The package system of claim 172, wherein the contact lens body is produced using wet cast molding.

176. (Previously presented) The package system of claim 172, wherein the water soluble polymer component in the contact lens body is physically immobilized by the hydrophilic polymeric material.

177. (Previously presented) The package system of claim 172, wherein the water soluble polymer component and the hydrophilic polymeric material form an interpenetrating network or a pseudo interpenetrating network.

178. (Previously presented) The package system of claim 172, wherein the hydrophilic polymeric material is obtained by polymerization of at least one hydrophilic monomeric component and at least one cross-linking monomeric component.

179-185. (Cancelled)

186. (Previously presented) The package system of claim 172, wherein the polyalkylene glycol is polyethylene glycol.

9. EVIDENCE APPENDIX

(NONE)

10. RELATED PROCEEDING APPENDIX

(NONE)

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